COMPARISON OF EXTENDED NASOLABIAL FLAP VERSUS BUCCAL FAT PAD GRAFT IN THE SURGICAL MANAGEMENT OF ORAL SUBMUCOUS FIBROSIS- A PROSPECTIVE STUDY

A Dissertation submitted in
partial fulfillment of the requirements
for the degree of

MASTER OF DENTAL SURGERY
BRANCH – III
ORAL AND MAXILLOFACIAL SURGERY

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY
Chennai – 600 032

2010 - 2013

CERTIFICATE

This is to certify that ***Dr. SANDEEP B. PATIL****, P.G. Student (2010-2013) in the Department of Oral and Maxillofacial surgery, Tamil Nadu Government Dental College and Hospital, Chennai-600 003, has done dissertation titled* ***"COMPARISON OF EXTENDED NASOLABIAL FLAP VERSUS BUCCAL FAT PAD GRAFT IN THE SURGICAL MANAGEMENT OF ORAL SUBMUCOUS FIBROSIS- A PROSPECTIVE STUDY"*** *under our direct guidance and supervision in partial fulfillment of the regulation laid down by The Tamil Nadu Dr. M. G. R. Medical University, Chennai, for MDS, Branch-III, Oral and Maxillofacial Surgery Degree Examination.*

GUIDED BY

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DECLARATION

I, **DR. SANDEEP B. PATIL** do hereby declare that the dissertation titled "**COMPARISON OF EXTENDED NASOLABIAL FLAP VERSUS BUCCAL FAT PAD GRAFT IN THE SURGICAL MANAGEMENT OF ORAL SUBMUCOUS FIBROSIS- A PROSPECTIVE STUDY***"* was done in the Department of Oral and Maxillofacial Surgery, Tamil Nadu Government Dental College & Hospital, Chennai-600 003. I have utilized the facilities provided in the Government dental college for the study in partial fulfillment of the requirements for the degree of Master of Dental Surgery in the speciality of Oral and Maxillofacial Surgery (Branch III) during the course period 2010-2013 under the conceptualisation and guidance of my dissertation guide, **Prof. Dr. D.DURAIRAJ**, M.D.S. I declare that no part of the dissertation will be utilized for gaining financial assistance for research or other promotions without obtaining prior permission from the Tamil Government Dental College & Hospital. I also declare that no part of this work will be published either in the print or electronic media except with those who have been actively involved in this dissertation work and I firmly affirm that the right to preserve or publish this work rests solely with the prior permission of the Principal, Tamil Nadu Government Dental College & Hospital, Chennai 600 003, but with the vested right that I shall be cited as the author(s).

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Head of the Institution

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This agreement herein after the "Agreement" is entered into on this day-_____between the Tamil Nadu Government Dental College and Hospital represented by its **Principal** having address at Tamil Nadu Government Dental College and Hospital, Chennai - 600 003, (hereafter referred to as, 'the college')

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DR. D. DURAIRAJ, 52 years, working as **Professor** in the Department of Oral & Maxillofacial surgery, at the college, having residence address at Sri Kumaran Illam, No.3/19, First Cross Street, Raghava Nagar, Moovarasampet, Chennai.600 091. (herein after referred to as the Principal investigator')

And

Dr. SANDEEP B. PATIL, aged 28 years, currently studying as **Post Graduate Student** in the Department of Oral & Maxillofacial surgery, Tamil Nadu Government Dental College and Hospital, Chennai-03 (herein after referred to as the 'PG Student and co- investigator').

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1.

2.

ACKNOWLEDGEMENT

I am extremely grateful to my esteemed guide ***Prof.Dr.D.Durairaj M.D.S.,*** *Professor, Department of Oral and Maxillofacial Surgery, Tamil Nadu Govt. Dental College and Hospital, for his filial attitude, valuable guidance, encouragement, lending me his precious time and never ending patience, without which this study would not have been possible and also for constant inspiration throughout my postgraduation period.*

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Narrow border of language could never express my respect and gratitude to all the patients who co-operated with me for this study.

I dedicate this study to my grandparents, my parents, & my friends for their unconditional love and concern.

Last but not the least, I would like to seek the ***blessings of the Almighty*** *without whose grace, this endeavour wouldn't have been possible.*

INSTITUTIONAL ETHICAL COMMITTEE

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R.C.No. 0430/DE/2010 Date: 27-03-2012

Title of the Work	"Comparison of extended nasolabial flap versus buccal fat pad graft in the surgical management of Oral submucous fibrosis – A Prospective Study"
Principal Investigator:	Dr. Sandeep B. Patil, II Year PG Student
Department	Department of Oral & Maxillofacial Surgery

The request for an approval from the Institutional Ethical Committee (IEC) was considered for the following on the IEC meeting held on 25-01-2012 at the Principal's Chambers, Tamil Nadu Government Dental College & Hospital, Chennai-3.

"Advise to proceed with the study"

The Members of the Committee, the Secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the Principal Investigator.

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LIST OF ABBREVIATIONS USED

(In alphabetical order)

ASA	American Society of Anaesthesiologists
BFP	Buccal fat pad
cm	Centimeters
gm	Grams
ml	Milliliters
mm	Millimeters
NLF	Nasolabial flap
OSMF	Oral submucous fibrosis

LIST OF CONTENTS

Background, aim and objectives

Oral submucous fibrosis is a chronic progressive premalignant condition, characterized by gradually increasing fibrosis of sub mucosa resulting in trismus thereby, limiting mouth opening. Various surgical modalities have been tried in the surgical management, but each has its own limitations. In the present study, extended nasolabial flap and buccal fat pad graft have been used for reconstruction after release of fibrosis. These two methods have been compared and assessed for their role in improving the mouth opening post operatively.

Methods

The study group consisted of 8 patients with bilateral clinically and histopathologically proven cases of oral submucous fibrosis. Group 1 (extended nasolabial flap) was compared with group 2 (buccal fat pad graft) post operatively for mouth opening up to 3 months follow up.

Results

In the present study, buccal fat pad graft proved to give better results as the interposition material as it has good patient acceptance, rapid epithelization, minimal donor site morbidity and minimal intra and postoperative complications.

Interpretation & conclusion

Based on the present study, use of buccal fat pad graft following excision of fibrotic bands, in the management of oral submucous fibrosis gave better results with respect to postoperative mouth opening.

Key words: buccal fat pad, oral submucous fibrosis, extended nasolabial flap, mouth opening.

INTRODUCTION

'Oral submucous fibrosis' (OSMF) is a well known entity described since the time of Sushruta as 'Vidari'.[1] In modern literature, this condition was first described by Schwartz as 'atrophica idiopathica mucosa oris' in 1952.[2] The term 'oral submucous fibrosis' was coined by Joshi in 1953.[3]

Oral submucous fibrosis is an insidious, chronic, disabling disease that affects entire oral cavity, sometimes pharynx and rarely larynx. It is characterised by blanching and stiffness of the oral mucosa which leads to progressive limitation of mouth opening and intolerance to hot and spicy food.[4] With further progression, it leads to difficulty in mastication, speech, and swallowing. It is most commonly seen in the Indian subcontinent with prevalence in south east asia ranging from 0.04% - 24.4%.[5] Etiology for this condition is considered as multifactorial with a high incidence associated with consumption of areca nut.[6]

The precancerous nature of this condition was first described by Paymaster in 1956.[7] It is an established precancerous condition with high malignant transformation risk (1.9% -7.6%).[8,9,10]

The treatment methods for oral submucous fibrosis have been palliative and concentrated to improve mouth opening and relieve the symptoms. Conservative medicinal treatment is not useful in advanced cases where surgical treatment is the treatment of choice. Severe degree of trismus is a challenging surgical problem. Various surgical treatment modalities have evolved but the mainstay is release of fibrosis by excision of fibrous bands with or without grafts. Reconstruction of the defect after incision and release of fibrous bands is done with variety of options such as skin grafts,[11] island palatal mucoperiosteal flap,[12] bilateral tongue flap,[13] the superficial temporal fascia flap with split thickness skin graft,[14] radial forearm

flaps,[15,16,17] flaps from anterolateral thigh,[18]artificial dermis,[19] buccal fat pad graft[20] and nasolabial flaps.[21]

In severe trismus cases, bilateral coronoidectomy and temporalis myotomy can be performed to relieve the trismus and enhance the mouth opening.[22]

The buccal fat pad has become a well-accepted graft for reconstruction of intraoral defects. It is simple, reliable and convenient graft for reconstruction of small to medium size defects of palate, gingival sulcus, alveolus and buccal mucosa.[20,23,24,25] It is easy to access and has rich blood supply.

The buccal fat pad was first mentioned as an anatomic element by Heister in 1732. It was first described by Bichat in 1802[26]. Scammon first described the anatomy of buccal fat pad followed by Goughran. Egyedi[27] was the first to report for using it for oral reconstruction. Tideman[28] et al described the use of buccal fat pad as a pedicled graft in reconstruction of oral cavity defects. In 1988, Vuillemin[29] et al used buccal fat pad in immediate reconstruction of maxillary surgical defects as a pedicled flap. Ho[30] obtained successful results in reconstruction of palatal and cheek defects with use of buccal fat pad. Dubin[31] and Stuzin[32] gave detailed anatomy of buccal fat pad and its use in orofacial reconstruction.

The nasolabial flap has proved to be efficacious and reliable in reconstruction of head and neck defects. It has been used for reconstruction of upper lip, nasal ala, septum, columella as well as for the intraoral defects[33,34,35] of the buccal mucosa, floor of the mouth, tongue and gingival sulcus as a single staged or two staged procedure. Flap elevation is quick and simple with minimal donor site morbidity and rapid postoperative rehabilitation. The proximity to the defect, preservation of function and least distortion of anatomy make it favourable choice.

The subcutaneous pedicled nasolabial flap was first described in the works of Sushruta in 600 BC. Thereafter for centuries, it was primarily used for external nasal reconstruction. A full thickness cheek flap tunneled through a transbuccal incision was described by Thiersch[36] in 1868. In modern times, Esser[37] and Ganzer[38] revived its use in various reconstructive procedures. Esser (1918) was the first to describe a flap consisting of skin only, which subsequently required a second procedure to divide the pedicle and inset the flap. The first single stage de-epithelized nasolabial flap was described by Wallace[39] (1966) for the closure of a palatal defect. In order to avoid the bulk of the deep epithelized pedicle in the tunnel and to provide more mobility, a one-step arterialized island flap was designed by Rose[40] (1981). Many variations have been described since then.

This study was undertaken to compare the post-operative results of reconstruction with extended nasolabial flap to those of reconstruction with buccal fat pad graft in terms of achieving acceptable mouth opening and reduction of symptoms after release of fibrosis.

AIM AND OBJECTIVES

AIM OF THE STUDY

To evaluate the application of extended nasolabial flap versus buccal fat pad graft in the surgical management of oral submucous fibrosis.

OBJECTIVES

1. To relieve the trismus and to achieve the optimum mouth opening.
2. To improve the masticatory efficiency and speech of the patient.
3. To reduce the long term morbidity and mortality of the patient.

SURGICAL ANATOMY

Surgical anatomy of buccal fat pad

Buccal fat pad is a supple, lobulated, biconvex specialised fatty tissue that lies in the masticator space between masseter and buccinator muscles. It is covered by a delicate fascial envelope.[41,42] It begins to appear at approximately third month of fetal life around the venous plexus that connects the orbital veins and superficial veins of the face. Its formation is completed before birth and persists into adult life.[28,43] It resembles orbital fat in appearance and function.

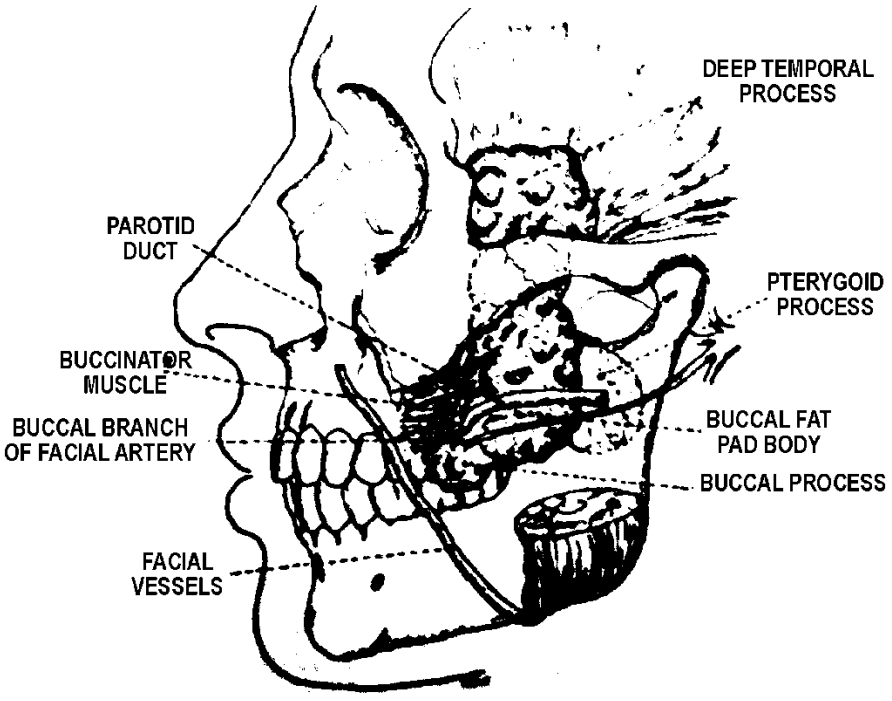
Buccal fat pad has a central body which is divided into three lobes: anterior, intermediate and posterior. Each lobe is encapsulated by an independent membrane and separated by a natural space. It has four extensions: pterygopalatine, temporal, pterygoid and buccal. The central and buccal extensions account for half of the total volume of buccal fat pad and are easily accessible through the oral cavity.[25,44] Buccal fat pad is fixed by six ligaments to the maxilla, posterior zygoma, inner and outer rim of infraorbital fissure, temporalis tendon and buccinator membrane.[45]

It has a rich blood supply through the small branches of the facial artery, internal maxillary artery, and superficial temporal artery and vein by an abundant network of vascular anastomosis which allow it to be used as an axial pattern pedicled flap.[46]

The mean volume of buccal fat pad in males is 10.2 ml with a range from 7.8 - 11.2 ml. In females, it is 8.9 ml with a range from 7.2 – 10.8 ml. The mean thickness is 6 mm and mean weight is 9.7gm. When properly dissected and mobilised it provides a 7×4×3 cm pedicle graft which can be utilised to close the defects up to 3×5 cm without compromising blood supply.[24,28,41,] The size of buccal fat pad is fairly

constant among different individuals regardless of the overall body weight and fat distribution.

Buccal fat pad fills deep facial spaces and functions as gliding pad. They also provide protection and cushion to deep facial neurovascular structures.



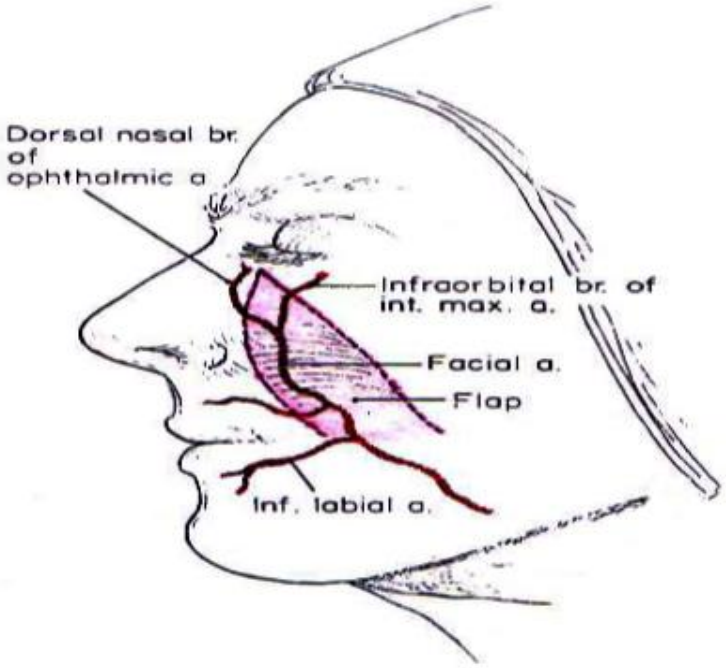
Anatomy of buccal fat pad

Surgical anatomy of extended nasolabial flap

Naslolabial fold is the area of junction between the cheek and lip aesthetic units. There is an area of redundancy that extends from the inner canthus to the inferior margin of the mandible, especially in old patients. This area is generally hairless except for the lower cheek in males and is considered the donor area for the nasolabial flaps.[47] The Superficial musculoaponeurotic system fascia is a fan like fascia that envelops the face and provides a suspensory sheet. It connects to the fascial musculature in the nasolabial, perioral, and periorbital regions.

The vascular anatomy of the nasolabial flaps is based on the angular artery (a branch from the anterior facial artery), the infraorbital artery, the transverse facial artery and the infratrochlear artery. Because of the rich vascular supplies and the free anastomosis between the terminal branches of the supplying vessels of the flap; superior, inferior, medial, and lateral based flaps can be raised.[48] Due to rich sub dermal plexus the flap can be used either as a random flap or as an axial pattern flap. A subcutaneous pedicled flap can also be raised as laterally or inferiorly based.[49]

In any procedure around the nasolabial area, the facial nerve is not at risk as it is deep to the muscle layer.



Vascular supply of nasolabial flap

REVIEW OF LITERATURE

J. C. Paymaster et al[7] (1956): In his study from 1941 to 1947, author found 650 patients had cancer of buccal mucosa from a total of 3627 cases with malignant intraoral tumours. He found that cancer of tongue was most common followed by cancer of buccal mucosa. Malnutrition with subsequent avitaminosis and long term chewing of betel nut with tobacco were evaluated as predisposing factors. Author observed pigmentation of the mucous membrane and localised submucous fibrosis affecting mainly soft palate, hard palate and tonsillar fossa. He observed that initial complaints were severe burning in affected areas and inability to take spicy food. In approximately one third of cases a slow growing squamous cell carcinoma developed in the affected region.

Pindborg JJ, Sirsat SM[73] (1966): Authors defined the condition and were the first to divide oral submucous fibrosis depending only on histopathological features alone as very early stage, early stage, moderately advanced and advanced stage.

Gewirtz H.S., Eilber F.R., Zarem H.A.[67] (1978): Employed nasolabial flaps in eight patients who had undergone resection of floor of the mouth, gingiva, alveolar ridge and mandible followed by primary reconstruction. Three patients had presented with primary carcinoma, three with osteoradionecrosis, one with failure of prior reconstruction and one with both recurrent disease and osteoradionecrosis. All the flaps provided excellent coverage, which survived subsequent irradiation and reoperation in three patients. They stated that the advantages of nasolabial flap include an excellent dual blood supply from facial and ophthalmic arteries, minimal cosmetic deformity and appropriate consistency for reconstructive purposes and minimal cosmetic deformity.

Gupta D.S., Gupta M.K., Golhar B.L., et al.,[79] (1980): Reviewed the literature on oral submucous fibrosis and classified oral submucous fibrosis clinically into 4 stages with increasing intensity of trismus.

i. Very early stage: the patients complain of burning sensation of mouth or ulceration without difficulty in opening the mouth.

ii. Early stage: Along with symptoms of burning sensation patient complains of slight difficulty in opening the mouth.

iii. Moderately advanced stage: The trismus was marked to such an extent that patient cannot open his mouth more than 2 fingers width, therefore experiences difficulty in mastication.

iv. Advanced stage: Patient was undernourished, anaemic and had a marked degree of trismus and/or other symptoms as mentioned above.

They treated 15 patients by either microwave diathermy (MWD) alone or Vitamin A and Vitamin B complex tablets and Inj. Hydrocortisone or combination of both for comparative improvement and they found MWD to be of much value in early as well as moderately advanced stages of oral submucous fibrosis. In very advanced cases the use of microwave diathermy was very poor and without any satisfactory result. The author concluded that this therapy may be attempted in all the early stages and moderately advanced stages of oral submucous fibrosis.

Pindborg J.J.et al[81] (1980): In their study of incidence and early forms of OSMF in Ernakulam district of Kerala showed a yearly incidence of OSMF per 100,000 to be 13. It was found that all patients presented with OSMF chewed areca nut. Observation of 11 cases of OSMF preceded by blanched mucosa suggested that

blanched mucosa alone or combined with other clinical symptom may represent early stages of OSMF and some biopsy specimens with clinical diagnosis of leukoplakia and lichen planus showed histopathological changes suggestive of oral submucous fibrosis.

Daniel J.C. Yen[11] (1982): Compared surgical resection of fibrotic bands with and without split thickness skin graft in the surgical management of oral submucous fibrosis in a 4 year follow up study. He found that cases treated by cutting of fibrotic bands showed only further scar formation and recurrence of trismus whereas those treated with 0.016 inch split thickness skin graft showed the satisfactory results with decrease in trismus and preservation of elasticity of grafts.

Murti P.R, Bhonsle R.B, Pindborg J.[8] (1985): In this they have studied 66 patients with oral submucous fibrosis followed up for a period of 17 years. The present analysis showed that submucous fibrosis possesses a high degree of malignant potential. Also with a 2 year increase in the observation period, malignant transformation rose from 4.5% to 7.6%. However, it is known that the peak incidence of this condition is in the range of 35-54years age group. Correspondingly it is likely that cancer development in this condition occurs in higher age groups.

They concluded that oral cancer developed in 5 (7.6%) patients. The malignant transformation rate in the same sample was 4.5% over 15 year's observation period (median 8 years). These findings impart a high degree of malignant potential to this condition.

Canniff J.P., Harvey W., Harris M.[50] (1986): Analysed 44 patients with OSMF and demonstrated genetic predisposition of the disease involving the HLA antigens A10, DR3, DR7 and probably B7 and the haplotypic pairs A10/DR3,B8/DR3

and A10/B8. All the cases were surgically treated by excising the fibrous bands and split-thickness skin grafting following bilateral temporalis myotomy or coronoidectomy. An inter-incisal opening of 35-40 mm was achieved in all the cases and the patients were subjected to daily opening exercises and nocturnal props for further period of 4 weeks with good results. Based on immunological studies, they postulated that oral submucous fibrosis was an autoimmune disease due to the female bias, age of onset (mean 30.1years), alteration in serum immunoglobulins.

The incidence of autoantibodies and the involvement of DR locus in the genetic predisposition. They also stated that betel nut extracts such as arecoline, stimulated fibroblast proliferation and collagen synthesis in vitro. Furthermore, the flavanoid catechin and tannins from betelnut stabilized collagen fibres and render them resistant to degradation. Based on these findings, they concluded that the study provided the valuable model for studying the role of genetic control of the immune response in the regulation of connective tissue turnover.

Tideman H., Bosanquet A. and Scott J.[28] (1986): Reported 3 cases where buccal fat pad was used as a pedicled graft to cover the surgical defects caused by excision of different carcinomas in head and neck region with satisfactory results. Postoperative radiotherapy did not have any deleterious effects on the survival of buccal fat pad grafts, but was asked to defer the radiotherapy until complete epithelization of graft has taken place. It was advised that buccal fat pad should adequately cover the defect and should not be sutured under tension and patient should be on liquid diet until soft tissue healing to avoid postoperative complication like infection and incomplete epithelization.

Glenn Morawetz, Nick Katsikeris, Simon Weinberg, et al[58] (1987): Authors reported two cases of oral submucous fibrosis. The diagnosis was confirmed

histologically and both patients were treated with excision of fibrotic bands and subsequent placement of split thickness skin graft. Immediate relief of trismus was observed in both cases which gradually increased with physiotherapy.

However, loss of maximal mouth opening secondary to cessation of physiotherapy was seen in one patient. Since surgical therapy probably did not address the etiology of oral submucosal fibrosis and assuming that the process continues, the authors have stressed on direct efforts towards maintaining maximal mouth opening and regular monitoring for development of cancer, since there is higher incidence of malignancy in such patients.

Kavarana N.M., Bhathena H.M.[69] (1987): Bilateral full thickness nasolabial flaps were used successfully in three patients to give long-term relief of the severe trismus caused by oral submucous fibrosis. The flaps were set into defects created by incision of the oral mucosa. The postoperative rehabilitation was compared favourably with other methods and authors have advocated the technique for all cases of submucous fibrosis requiring correction of severe trismus.

Gupta D., and Sharma S.C.[4] (1988): Reported the outcome of treatments of oral submucous fibrosis in 200 patients in whom biweekly submucosal injections of a combination of chymotrypsin, hyaluronidase and dexamethasone administration for 10 weeks proved successful, except in 14 patients who presented with advanced form of the disease. They observed that maximum improvement using submucosal injections was obtained by 10 weeks, and no further improvement was seen even when the therapy was continued on a monthly basis for a year. In 14 patients who were unresponsive to this conservative therapy were subjected to surgical excision of fibrotic bands and submucosal placement of bits of fresh human placenta in the affected areas. Biweekly submucosal injections of dexamethasone administered for 4

weeks gave definite relief from symptoms. All 14 patients treated with placental grafts had early and significant relief of symptoms.

Hynes B., Boyd J.B.[78] (1988): Performed anatomic dissection on 12 cadaveric specimens and microangiography on 6 others and confirmed that the facial artery passes deep to the facial mimetic muscles and is not normally included within the flap. Although the vasculature of the flap is technically random the small vessels of the subdermal plexus are generally oriented along its long axis giving it a 'degree of axiality'. They quote two possible reasons for reliability of the flap. 1) Abundant dermo-subdermal plexus supplying the whole area, 2) This vascularity is not haphazard but, exist as axiality of random flap ensuring good perfusion to the most distal parts of the flap.

The major contributing vessels to the subcutaneous arterial network include facial artery, transverse facial artery and likely anastomotic contribution from contralateral superior and inferior labial vessels.

Pogrel et al.[74] (1998): Performed a cadaver dissection study to investigate the anatomy of the nasolabial fold with a view to explaining the problems of surgical softening or elimination of the fold. The nasolabial fold is absent in the newborn and deepens and becomes more prominent as age advances. The nasolabial fold is defined by structures that support the buccal fat pad and hold it above the fold. This appeared to be a combination of muscle bundles that run both across and parallel to the fold and also by fibrous septae supporting the fat pad.

This had implications for the development of surgical procedures to soften or eliminate the fold, which must separate the muscles from the dermis of the fold and allow the fat to descend and soften the fold. They suggested that development of surgical techniques taking into account the anatomical structure of the nasolabial fold

wound be a logical development.

Vanwyk C.W., et al.,[75] (1990): Carried out an electron - microscopic study of the collagen fibrils for comparison of 11 specimens of moderately advanced and advanced stages of OSMF with 15 control specimes. They noted that the collagen in case of OSMF patients were densely packed bundles in the lamina propria, reaching close to the epithelial - connective tissue junction, to blood vessel walls, salivary glands and muscle fibres, were identified to be the thinner type III collagen fibrils. Immunofluorescent microscopy and special staining with sirius red and polarisation microscopy demonstrate both types, confirming that type I collagen forms the bulk of the collagen and that type III is localised at the sites mentioned above. The author concludes that although there is excessive increase of collagen, especially type I, in submucous fibrosis, the fibrils are still morphologically normal.

Borle R.M., and Borle S.R.[62] (1991): Divided 326 patients into two groups - Group I had 160 patients with ages ranging from 15-58 years. The group I further divided into A, B, C, D according to age as the disease is more rapid in younger patients. Group-I patients were given biweekly submucosal injections of triamcinolone in lidocaine 2% and hyaluronidase 1500 IU on a biweekly basis, for 4 weeks and followed on monthly basis. Group-II had 166 patients were given vitamin A chewable tablets 50,000 IU/O.D., oral ferrous fumarate 200mg/O.D. and topical beta-methasone drops (0.5mg/ml) / 6 hourly / 3 weeks.

A follow-up for 1 year showed that Group-I patients had symptomatic relief within 1 week of treatment, but no improvment in trismus. The disease invariably reactivated in 3-4 months. During the follow up, 14 patients developed infection.

In Group-II – In 2 weeks symptomatic relief was observed. Patients felt relaxation in the stiffness of buccal mucosa, however there was no improvement in

trismus. Relapse was seen in 4-6 months but the number of cases were less when compared to group-I.

Thus it was concluded that conventional treatment with injections proved hazardous whereas conservative treatment was found to be safe and both treatment modalities were purely palliative.

Pillai R., Balaram P., and Reddiar K.S.[6] (1992): Stated that OSMF is multifactorial and appears in people having a genetic predisposition which could render the oral mucosa more susceptible to chronic inflammatory changes on exposure to carcinogens, which include betel quid components including tobacco. The authors also relate the role of viruses and their oncogenic potential to OSMF. Immune dysfunction is a common factor and could be related to any of the factors mentioned above and based on these factors, the author has suggested a possible model for studying genetic-environmental-immunologic-nutritional interactions in pathogenesis of oral submucous fibrosis.

Samman N[43] (1993): Author in his retrospective evaluation of 29 patients with malignancies, beningn tumors, oroantral fistulas, osteoradionecrosis and other defects received pedicled BFP grafts to reconstruct the acquired defects in the oral cavity. Of the total 29 cases, 28 healed well without complications. Healing of uncovered BFP took place within 2-3 weeks. From the results of this series it was concluded that the use of BFP for reconstruction of appropriate defects in the mouth is worthy of consideration and use of BFP is a logical, convenient and reliable method of reconstruction of oral defects up to 4cms in diameter in the ipsilateral side of the soft palate and posterior alveolar region the maxilla.

Khanna J.N., Andrade N.N.[12] (1995): Reported their experience with 100 cases of OSMF and found that areca nut was the primary cause of this entity. All lesions were biopsied and a clinico-histopathological staging was proposed. Very early and early stages were treated with conservative approach whereas advanced cases could be successfully treated with only surgical intervention. They described a new surgical technique of a palatal island flap based on greater palatine artery in combination with temporalis myotomy and bilateral coronoidectomy in 35 cases.

They achieved a mean opening of 35mm intra-operatively and on a follow-up of 4 years the mean maximal opening was found to range from 34-35mm. All the donor areas healed well and none of the flaps underwent rejection or necrosis. The authors conclude that surgical treatment was the only solution in advanced cases and the technique of utilising palatal island flap was simple with promising results.

Lai D. R. et al.,[64] (1995): Conducted a retrospective study on a total of 150 patients with varying degrees of oral submucous fibrosis by either medical or surgical therapies. Medical treatment involved a) conservative oral administration of vitamin B complex, bluflomedil hydrochloride and topical triamcinolone 0.1% or b) conventional submucosal injections of a combination of dexamethasone and hyaluronidase, or c) combination of a) and b). The surgical group was treated by the excision of fibrotic tissue and covering the defect with split thickness skin, fresh human amnion or buccal fat pad grafts. Apart from these modalities the authors mention the use of bilateral full thickness nasolabial flaps in such cases but negate its use due to external facial scars, which was not acceptable to the patients. Surgical therapy lead to a significant improvement of trismus in severe limitation of mouth opening and was the treatment of choice for moderately advanced and advanced cases of oral submucous fibrosis.

The authors conclude that apart from surgical treatment, cessation of betel quid chewing before and after therapy combined with daily mouth opening exercises were mandatory for successful management.

Murti P.R., et al., (1995)[80]: Reviewed the etiology of oral submucous fibrosis with special reference to the role of areca nut chewing. They summarised and critically analysed the considerable body of evidence which implicated arecanut in the etiology of this condition and commented on the genetic susceptibility and autoimmunity related to the disease.

Lai Yeh C.Y.[20] (1996): Presented the application of the pedicled buccal fat pad graft in the surgical treatment of oral submucous fibrosis. In his study, 9 patients underwent surgical release of fibrotic bands with or without coronoidectomy to achieve a minimal inter-incisal mouth opening of 35mm following which the defects were covered with pedicled buccal fat pads. The authors noted satisfactory results in all but two patients who failed to follow post-operative physiotherapy. They achieved an average increase in the mouth opening by 19.1 mm over a mean follow up of 21.3 months. They noted that the technique was easy to perform and could be approached through the same incision. In addition BFP provided adequate bulk to cover the entire defect and epithelized by 2 to 3weeks with no incidence of breakdown or infection. They concluded that the technique was a logical, convenient and reliable option for the treatment of oral submucous fibrosis.

Ducic Y., Burye M.[76] (2000) : Described the successful use of pedicled nasolabial flaps in the reconstruction of various oral cavity defects with or without adjunctive microvascular free tissue transfer. Twenty eight flaps were performed in 18 patients, for reconstruction of defects in the anterior tongue, floor of mouth, palate

and retromolar trigone. All flaps healed without evidence of necrosis, infection or dehiscence. Patient satisfaction with this procedure was high. The use of the nasolabial flap appeared to provide an improvement in overall functional outcome.

They concluded that the inferiorly based nasolabial flap provided reliable coverage of intermediate size oral cavity defects when used alone. It could improve mastication and speech when used in conjunction with microvascular free tissue transfer for the reconstruction of large combined defects of the tongue and floor of mouth**.**

Haider S.M., et al.,[71] (2000): Performed a study on 325 patients suffering from oral submucous fibrosis. The purpose of this study was to investigate the association of location of bands in oral submucous fibrosis and extent of mouth opening. They staged the disease clinically and functionally.

Clinical staging:

I: Faucial bands only

II: Faucial and buccal bands

III: Faucial and labial bands

Functional staging:

Stage A: Mouth opening - 13 – 20 mm

Stage B: Mouth opening - 10 – 12 mm

Stage C: Mouth opening - < 10 mm

They found that all those who had labial band also had buccal bands, all those who had buccal bands also had faucial bands but 111 (42%) of those with buccal

bands did not have labial bands. They concluded that bands are common at the posterior region in mild cases of oral submucous fibrosis and as the disease increases in severity, are more likely to be found anteriorly as well.

Fu Chan Wei, Yang Ming Chang, Morten Kildal, et al[15] (2001): Authors introduced new surgical method for reconstructing bilateral buccal mucosa with two small radial forearm flaps. Their surgical method included complete release of fibrosis, and if necessary a bilateral coronoidectomy and temporalis muscle myotomy. Their study from 1997 to 1999 included 15 patients with moderate to severe trismus in which reconstruction was done with small radial forearm flaps. In their follow up all flaps survived except one with partial necrosis. Six flaps required minor revisions due to size redundancy. At an average 12 months follow up an inter-incisal distance of 33 mm was observed. Donor site morbidity was minimal except one case who developed dry gangrene of fingertips. Authors have experienced consistent good results with this method.

Haque M.F., Meghji S., et al[59] (2001): In their study investigated -

a) The effect of interferon gamma on collagen synthesis by arecoline stimulated oral submucous fibrosis fibroblasts in vitro (n=5).

b) The effect of intra-lesional interferon gamma on the fibrosis of oral submucous fibrosis patients (n=29).

c) The immunohistochemical analysis of pre and post treatment inflammatory cell infiltrates and cytokine levels in the lesional tissue (n=29).

The results showed that the increased collagen synthesis in vitro in response to arecoline was inhibited in the presence of interferon gamma (0.01 – 10.0 u/ml) in a dose related way. In an open uncontrolled study intralesional interferon gamma treatment showed improvement in the patients mouth opening from an inter incisal

distance before treatment of 21±7mm to 30±7mm immediately after treatment and 30±8mm 6 months later, giving a net gain of 8±4mm (42%).

Patients also reported reduced burning, dysaesthesia and increased suppleness of the buccal mucosa. The effect of interferon gamma on collagen synthesis appears to be a key to the treatment of these patients and intra-lesional injections of the cytokine may have a significant therapeutic effect on oral submucous fibrosis.

Lazaridis N. et al[77] (2003): Described the use of a single-stage unilateral subcutaneous pedicled nasolabial island flap, for reconstruction of defects of the anterior floor of mouth by raising the flaps as skin island relying on the pedicle of subcutaneous tissues. 9 flap procedures were performed on 9 patients for reconstruction of defects of anterior floor of mouth. All flaps healed without evidence of infection, dehiscence or necrosis and the flap provided improved functional integrity of the reconstructed area. The author concludes that this flap provides reliable coverage of small and intermediate sized defects of the anterior floor of mouth when used alone, improving the tongue mobility, articulation and deglutition.

J. Mokal, R.S. Raje, et al[14] (2005): Authors treated a total of 5 patients with severe submucous fibrosis using a new technique of release of fibrosis and reconstruction using superficial temporal fascia flap and split skin graft. All patients showed good mouth opening in the long term follow up. The incision line was hidden in the hair bearing area. There was no donor site morbidity. Authors observed that, a well vascularised superficial temporal fascia flap brings in good vascular supply to affected area and mucosa to improve its function.

J.T. Lee, L.F. Cheng et al[16] (2007): A total of 10 patients of advanced oral submucous fibrosis were treated with release of fibrosis, masticatory muscle

myotomy and coronoidectomy, and reconstruction with a bipaddled radial forearm flap. The preoperative mouth opening was 0-5 mm (mean 2.3 mm). Authors achieved mouth opening of 12-20 mm (mean 16 mm) after release of fibrosis and 32-42 mm (mean 35.5 mm) after further release via myotomy and coronoidotomy. The postoperative mouth opening was 18-38 mm (mean 28.2 mm) after a mean of 21 months follow up and the mean increase was 25.9 mm. arterial thrombosis was noted in one flap and flap revision was needed in two patients due to bulkiness. According to author, a bipaddled radial forearm flap, using a single donor site, can cover two separate buccal defects and obviate the need for a second free flap.

Borle RM, Nimonkar PV, Rajan R[21] (2009): A study was conducted on 47 consecutive patients (46 men and 1 woman aged between 18 and 44 years of age), were randomly selected with histologically confirmed oral submucous fibrosis. They all had interincisal opening of less than 25mm and were treated by bilateral release of fibrous bands, coronoidectomy or coronoidotomy and the resultant oral defects were reconstructed with extended nasolabial flap.

All patients had postoperative physiotherapy and were followed up for 2 years. Their interincisal opening improved significantly from a mean of 14mm (range 3-23) to a mean of 41mm (range 23-55), the transposed flap were widened from 10mm to the mean of 27mm after physiotherapy and four patients had unsatisfactory mouth opening because of poor compliance. The author concluded that the procedure was effective in the management of patients with oral submucous fibrosis, the main disadvantage being the extraoral scars.

Mehrotra D, Pradhan R, Gupta S[54] (2009): A total of 100 patients of oral submucous fibrosis were included in this study and randomly allocated to different

surgical groups, 25 patients per group. After excision of fibrous bands, group I had buccal fat pad graft, group II had tongue flap, group III had nasolabial fold flap and group IV had split skin graft for correction of mucosal defect created after incising the fibrous bands.

Buccal fat pad served as the best substitute, because it provided excellent function without deteriorating the esthetics. It offered ease of surgery, could be easily performed under local anesthesia as a day care procedure, had little postoperative morbidity and good patient acceptance. Tongue flap restricted the mobility of tongue in the immediate postoperative phase, causing discomfort to the patient and difficulty in speech. Nasolabial flap provided both function and esthetics and was extremely good in older patients, as it causes wrinkle lift owing to the resultant stretching of the skin, giving better esthetics in older age group. Mouth opening and function achieved with nasolabial flap was long term. The most unwanted thing associated with this flap was hair growth introrally. Esthetics and function achieved with split skin graft was good but showed some degree of relapse owing to contracture of the graft.

Jung Ju Huang, Chris Wallace, Jeng Yee Lin, et al[18] (2010): A total of 9 male patients with mean age of 45.8 years were treated between 2004-2006 for submucous fibrosis, who underwent surgical release of fibrosis, masticator muscle myotomy and coronoidectomy followed by reconstruction with two independent flaps based on individual perforators or septocutaneous vessels from one thigh. Of the 18 free flaps, 17 were successfully transferred. One free flap failure was observed. The mean preoperative interincisal distance was 9.6 mm and mean 1 month postoperative improvement was 18.4 mm. After 16.2 months, the mean improvement was 15.3 mm. Four flaps required debulking. One patient had postoperative recipient site infection and one had seroma formation. So instead of flaps from both thighs, authors harvested

two independent flaps from the same thigh to reconstruct bilateral buccal defects after release of submucous fibrosis.

M. C. Kothari, N. Hallur, et al[63] (2012): Authors evaluated coronoidectomy, masticatory myotomy and buccal fat pad graft in advanced cases of oral submucous fibrosis. A total of 10 patients were treated using this method followed by vigorous mouth opening exercises. After 12 months postoperatively a mean of 32.5 mm interincisal opening was achieved compared to a mean of 14.7 mm preoperatively. In one patient relapse was seen as the patient did not cooperate with the postoperative exercise regime.

Rohit sharma, G. K. Thapliyal et al[72] (2012): Authors treated 28 clinically and histologically diagnosed patients of oral submucous fibrosis who were divided into 2 groups, group 1 (n=15) and group 2 (n=13) corresponding to clinical stage III and stage IV, respectively. All the patients underwent incision of fibrotic bands and coverage of the defect with pedicled buccal fat pad. Authors analysed both the groups for mouth opening preoperatively and 1 year postoperatively, time taken for epithelialization of BFP, time taken for establishment of normal contour, and changes in symptoms 1 year after grafting.

The mean preoperative mouth opening was 19.6 mm (SD, 2.43) in group I and 12.92 mm (SD, 1.21) in group II. The mean postoperative mouth opening after 1 year was 35 mm in group I (SD, 1.96) and 31.76 mm in group II (SD, 1.97). The time taken for epithelialization of BFP was 4 weeks in group I and 5 weeks in group II. The mean time taken for establishment of normal contour after grafting was 12.25 weeks (SD, 1.42) in group I and 15.07 weeks (SD, 1.26) in group II. In 2 cases in group II, there was remission of painful ulcerations, burning sensation, and

intolerance to spices. Author has concluded that buccal fat pad functions well as a pedicled graft in the surgical management of oral submucous fibrosis.

METHODOLOGY

This prospective study was carried out in the Department of Oral and Maxillofacial Surgery, Tamil Nadu Government Dental College and Hospital, Chennai. This study included those patients who reported to our department with chief complaints of restricted mouth opening, burning sensation in mouth, intolerance to hot and spicy food or combination of all and were screened for clinical diagnosis of oral submucous fibrosis.

Inclusion criteria:

- Patients with moderately advanced or advanced stage of oral submucous fibrosis with inter-incisal mouth opening of less than or equal to 15 mm and with long standing positive history of habits.

- Patients in whom diagnosis is confirmed clinically, histopathologically and in whom any malignancy is ruled out.

- Patients with a high level of motivation to give up deleterious habits.

Exclusion criteria:

- Medically compromised patients (ASA class III and IV).

- Patients not willing for consent and long term follow up.

- Patients with history of surgical treatment for oral submucous fibrosis.

- Patients with clinical or radiological presentation of any other cause of trismus.

A total of 8 patients (6 men and 2 women) with age range from 21 to 65 years who fulfilled the above criteria were selected for study. These 8 patients were divided into two groups of four namely group 1 and group 2. In group 1 patients, reconstruction was planned with extended nasolabial flaps and in group 2 patients,

reconstruction was planned with buccal fat pad graft respectively. A detailed history was obtained from each patient especially regarding their habits and duration. Clinical examination, routine haematological investigations and radiographs were done for all patients.

All patients were explained about the procedure and limitations of the surgery and informed consent was obtained from each patient. Preoperative inter-incisal distance was measured using simple ruler and recorded in millimeters.

PROFORMA

Name of the Patient:

Age / Sex:

Date:

Address:

Phone No.:

O.P. No.:

1. Chief complaint (with duration):

2. History of presenting illness:

3. Medical History:

4. Family History:

5. Habits (with duration):

(Betel quid / Gutkha / Smoking / Alcohol /

or combination these four)

6. Clinical Examination:

- General Physical Examination:
- Local Examination:

- Hard tissue examination:
- Soft tissue examination:

- Oral Mucosa

  Appearance:

  Consistency:

  Fibrotic bands:

- Preoperative mouth opening (mm):

7. Investigations:

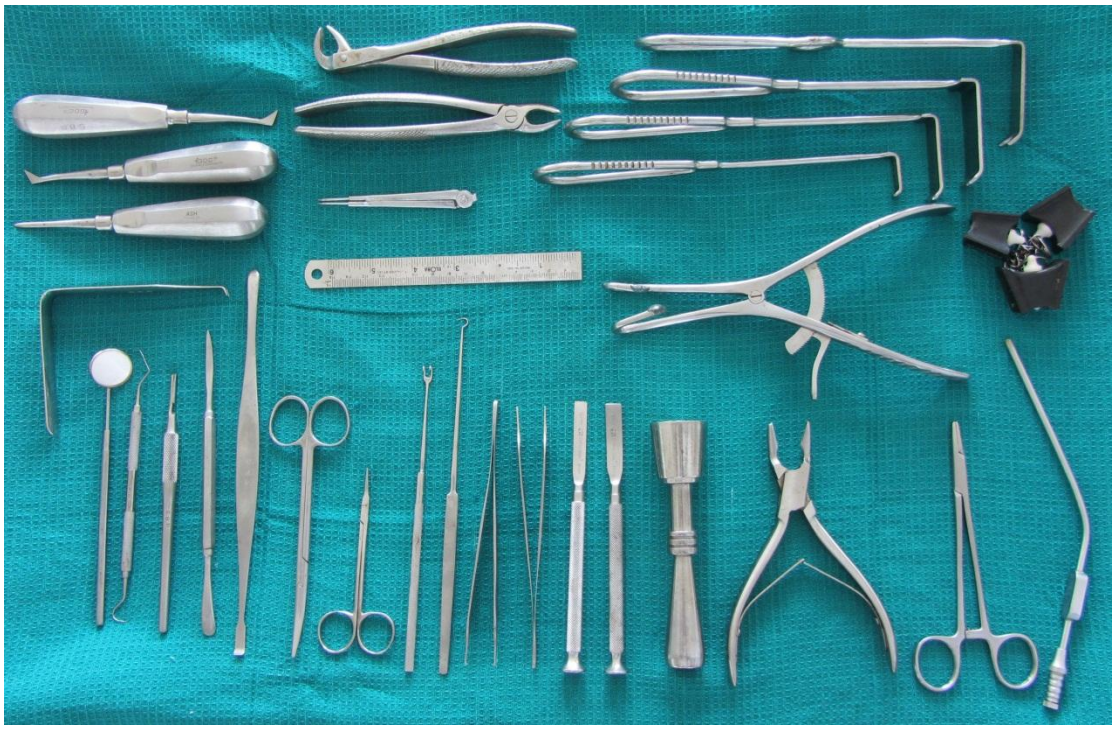
- Routine Haemogram
- Histopathological Examination
- Orthopantomogram

8. Details of Surgical Procedure

- Anaesthesia
- Surgical Incision
- Intra-operative mouth opening (mm)
- Graft Material used

9. Follow-up

- Mouth opening after seven days (mm)
- Mouth opening after fifteen days (mm)
- Mouth opening after one month (mm)
- Mouth opening after three months (mm)



Armamentarium

SURGICAL PROCEDURE

Anaesthesia:

All patients were treated under general anaesthesia through nasoendotracheal intubation using retrograde / blind nasal / fiberoptic method.

Incision and fibrous bands release:

Intraoral bilateral infiltration was given along the planned incision line with 1:2,00,000 epinephrine concentration. Incisions were made using number 15 Bard Parker blade on each side of buccal mucosa at the level of occlusal plane away from Stenson's duct orifice. Incisions extended from the corner of the mouth anteriorly to the anterior pillar of fauces, soft palate and / or pterygomandibular raphe posteriorly depending on the extent of fibrous bands felt by palpation. Blunt dissection and undermining was done until no restrictions were felt.

Achievement of optimum mouth opening:

Using Fergusson's mouth gag, mouth was forcefully opened to an acceptable range of 40-45 mm. Out of these 8 patients, 3 patients in whom inter-incisal mouth opening of less than 30 mm was achieved by incising the fibrous bands, coronoidotomy was done in 1 patient and coronoidectomy was done in 2 patients. Inter-incisal mouth opening of 40-45 mm was achieved for these three patients. Haemostasis was achieved in all patients.

Reconstruction with Extended nasolabial flap:

In group 1 patients, in whom reconstruction was planned with extended nasolabial flap, extractions of upper and lower third molars were done. In these patients, after incising the fibrous bands and achieving acceptable range of mouth opening, bilateral elliptical shaped nasolabial flaps were marked with methylene blue ink. Flaps extended from the tip of the nasolabial fold to the inferior border of the mandible. The medial incision line followed the nasolabial folds till the inferior third

and the width of the flap was kept 1.5-2 cm with medial and lateral limbs of the incision tapering at the ends. Bilaterally, flaps were raised in the plane of superficial musculoaponeurotic system from both ends to the region of central pedicle 1 cm away from the corner of the mouth. The diameter of the pedicle was roughly 1.5-2 cm.

A transbuccal tunnel was created near the region of modiolus. The flap was then transposed intraorally in tension free manner. The superior wing of the flap was sutured to the posterior edge of the defect while inferior wing was sutured to the anterior edge of the defect[21] using 3-0 monocryl suture material. Generous undermining of the donor site was done in the subcutaneous plane and layerwise closure done with 3-0 vicryl for deeper layer and 5-0 prolene for skin.

Reconstruction with buccal fat pad graft:

In group 2 patients, in whom reconstruction was planned by buccal fat pad graft after incising the fibrous bands and achieving acceptable range of mouth opening, buccal fat pad was approached through the postero-superior margin of the created defect. After blunt dissection, buccal fat pad was teased out gently with index finger until sufficient amount was obtained to cover the defect without tension. Buccal fat pad was then secured over the defect with 3-0 vicryl suture material using interrupted and mattress sutures.

Postoperative care and follow up:

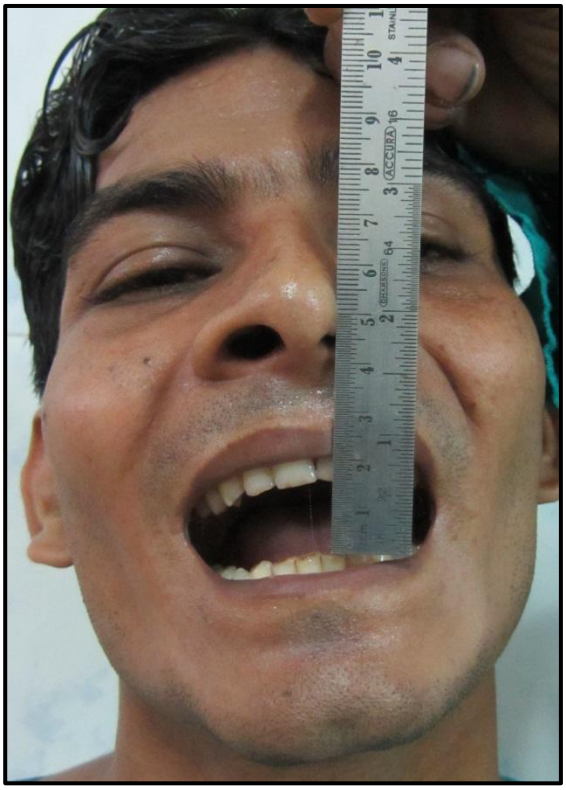
All the patients received prophylactic antibiotic coverage and nasogastric feeding for 1 week. Extra-oral sutures were removed on the seventh post-operative day for extended nasolabial flap patients. Initial physiotherapy was started within 48 hours post operatively with mouth opening exercises and placing mouth prop inter-incisally. After tenth postoperative day, intense physiotherapy was started using

Heister's mouth gag. Duration and frequency were increased later to achieve the intraoperative values.

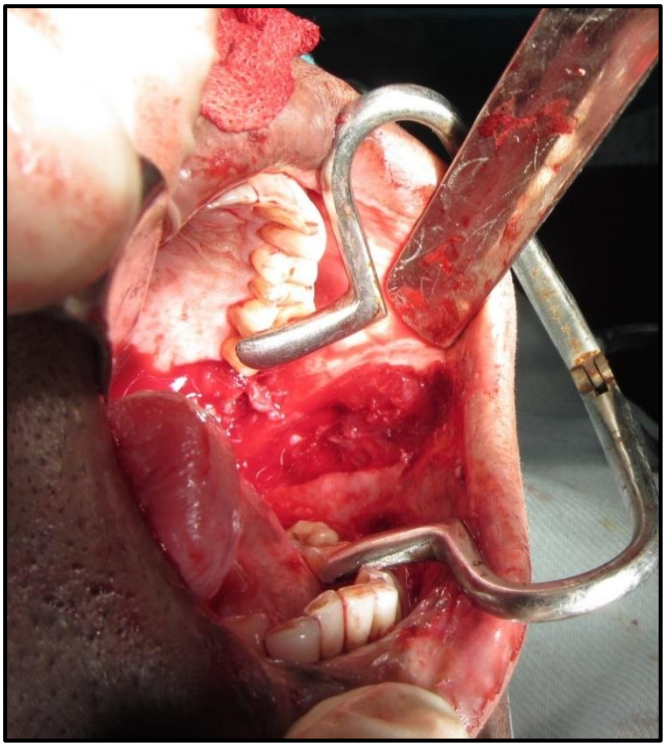
Patients were instructed and motivated to continue the physiotherapy themselves for 6 months and followed up. The inter-incisal mouth opening was recorded 1 month and 3 months postoperatively with simple ruler and recorded in millimeters during follow up period.

CASE REPORTS

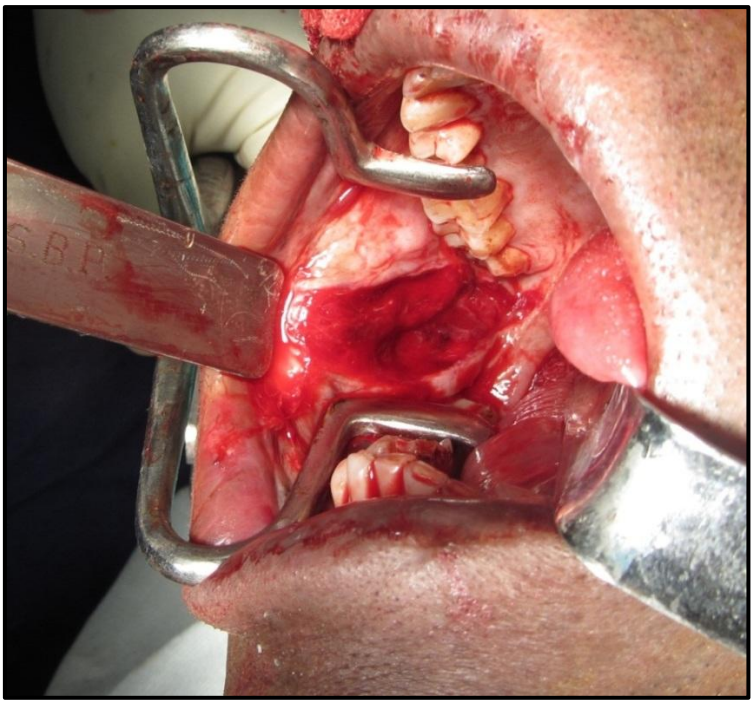
CASE REPORT- EXTENDED NASOLABIAL FLAP



Preoperative photograph

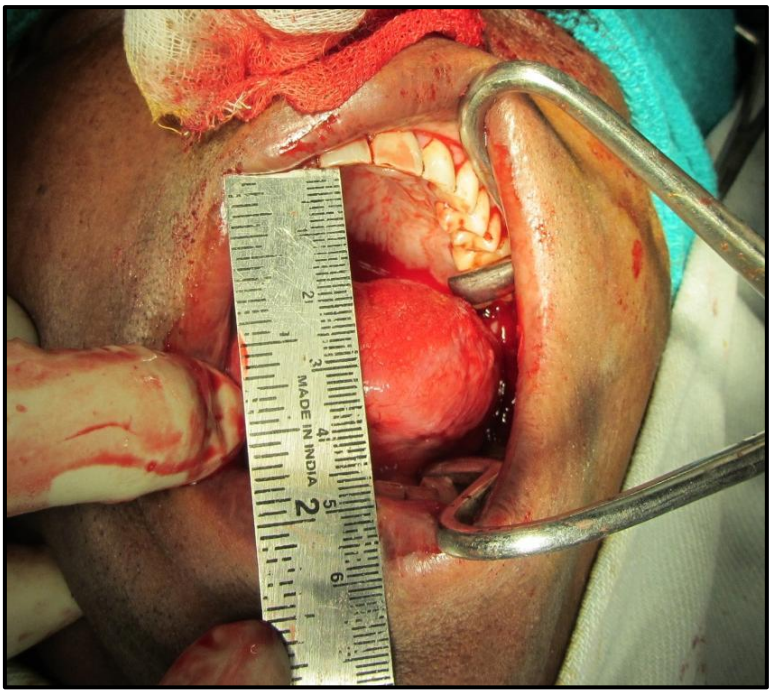


Incision and fibrous band release (Left side)



Incision and fibrous band release (Right side)

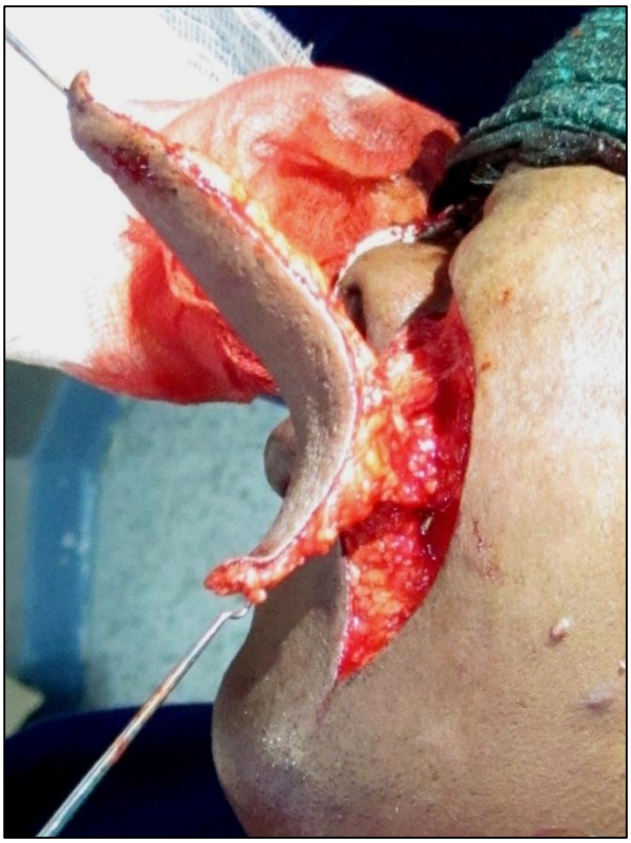
Coronoidectomy



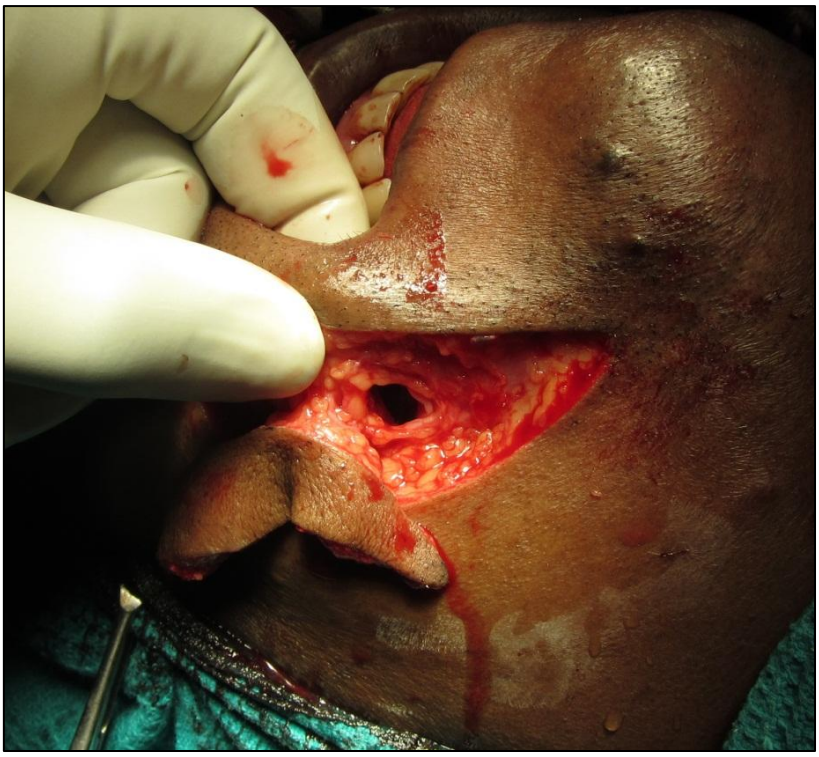
Mouth opening after incision of fibrous bands and bilateral coronoidectomy

Incision marking of extended nasolabial flap

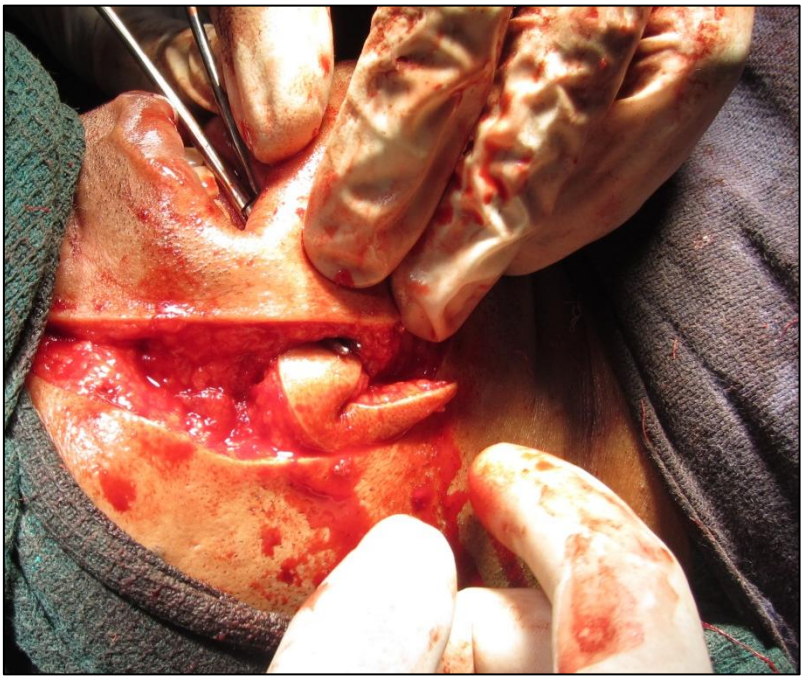
Elevation of flap on right side



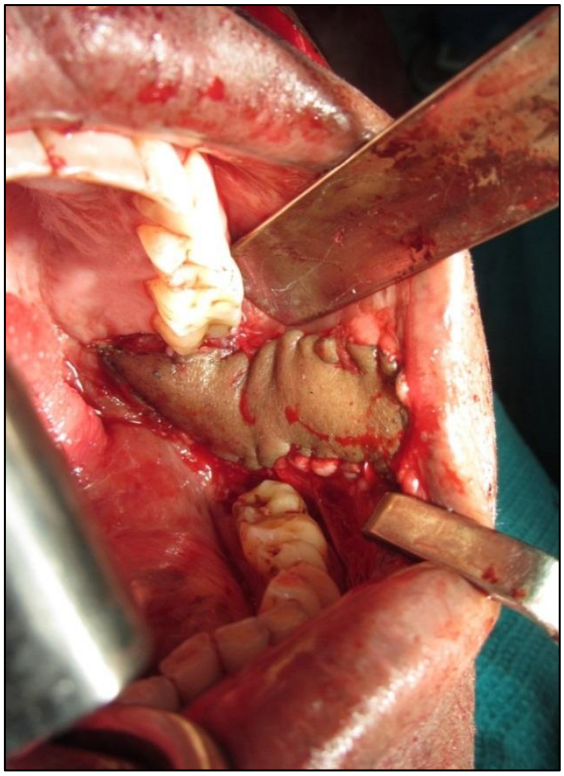
Elevation of flap on left side



Creation of transbuccal tunnel



Transposing the flap intraorally

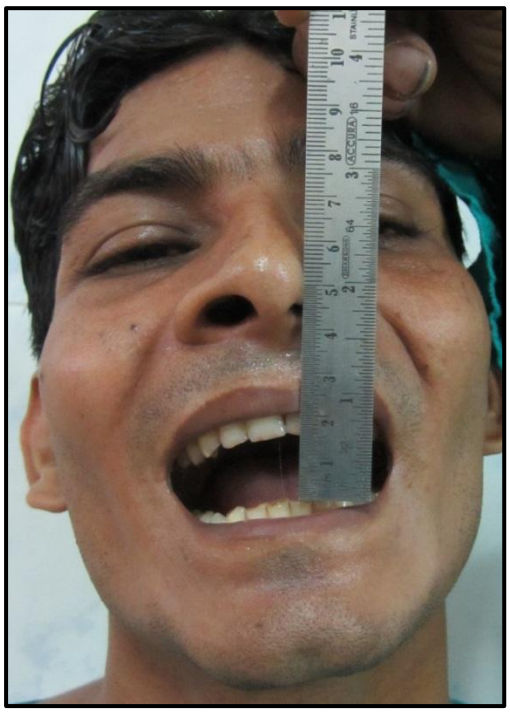


Flap sutured over the defect (Left side)

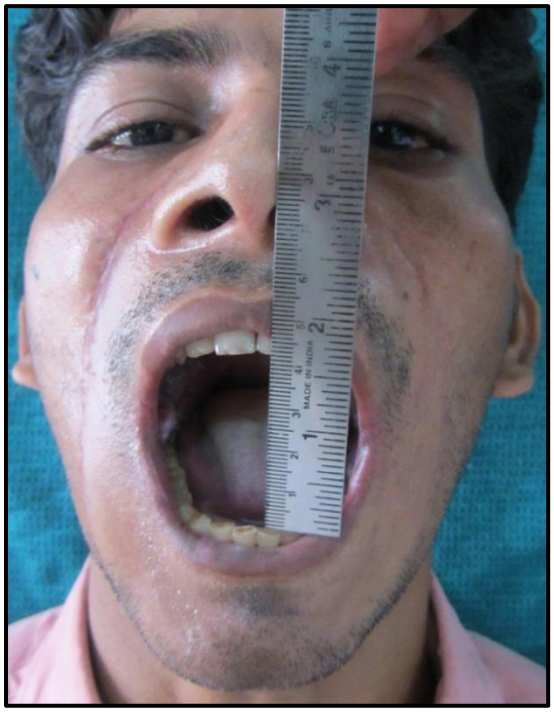
Flap sutured over the defect (Right side)

Extraoral suturing of donor site

Intraoral adaptation of flap after three months

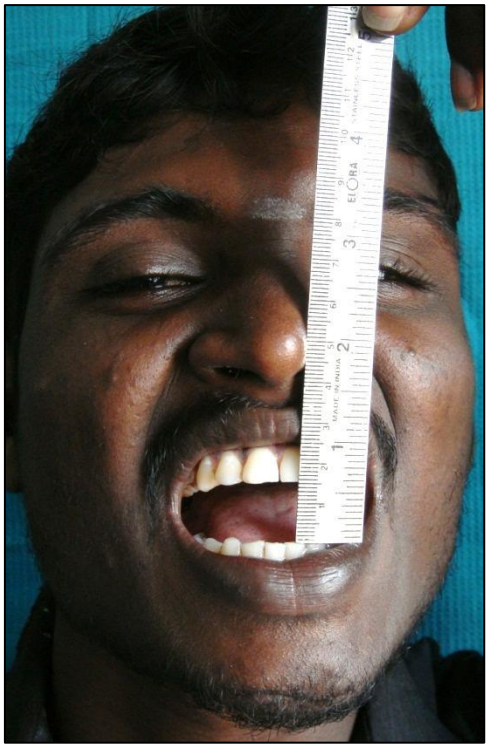


Preoperative photo



Postoperative photo after 3 months showing mouth opening of 43 mm and scars

CASE REPORT- BUCCAL FAT PAD GRAFT

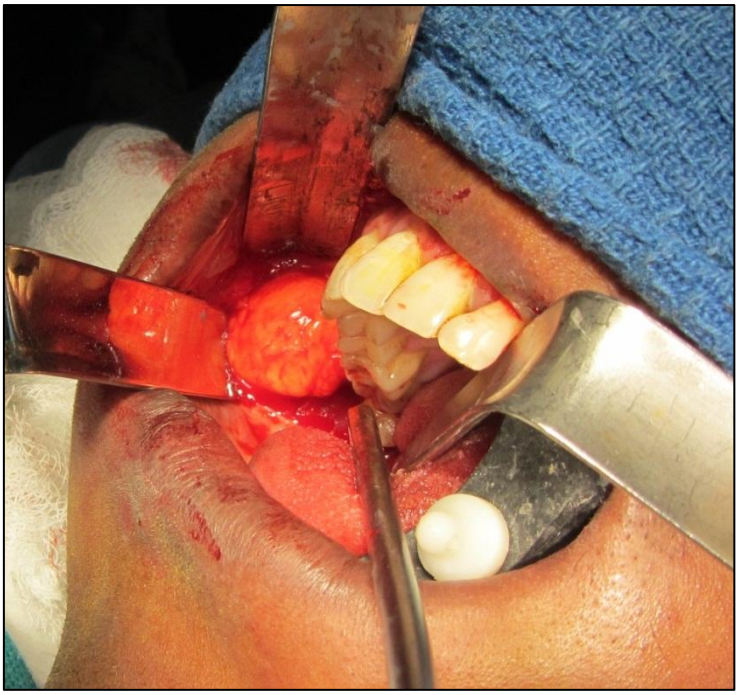


Preoperative mouth opening

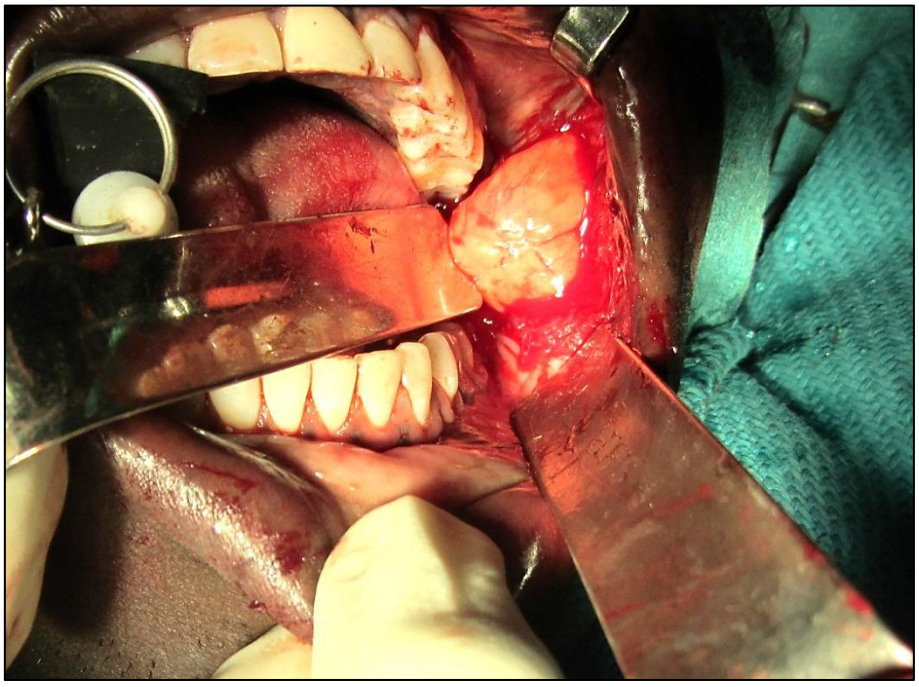
Incision and fibrous band release (Right side)

Incision and fibrous band release (Left side)

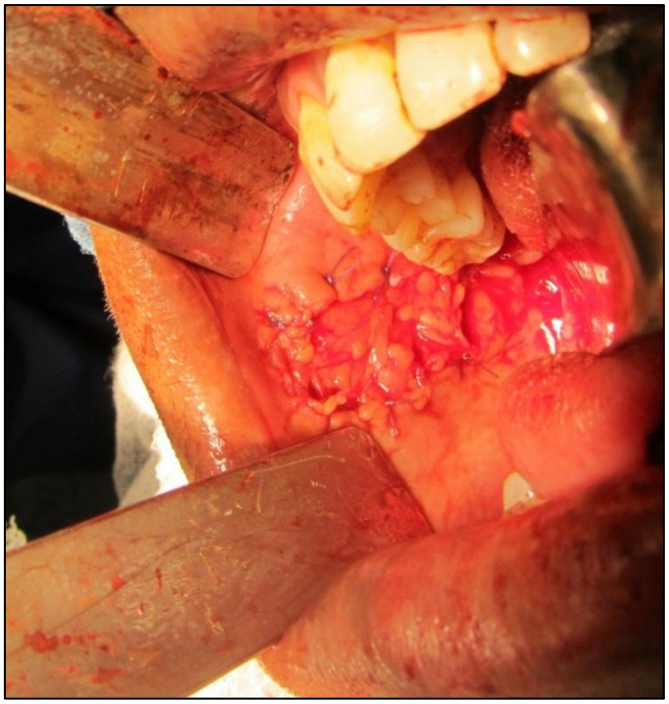
Mouth opening after incision of fibrous bands



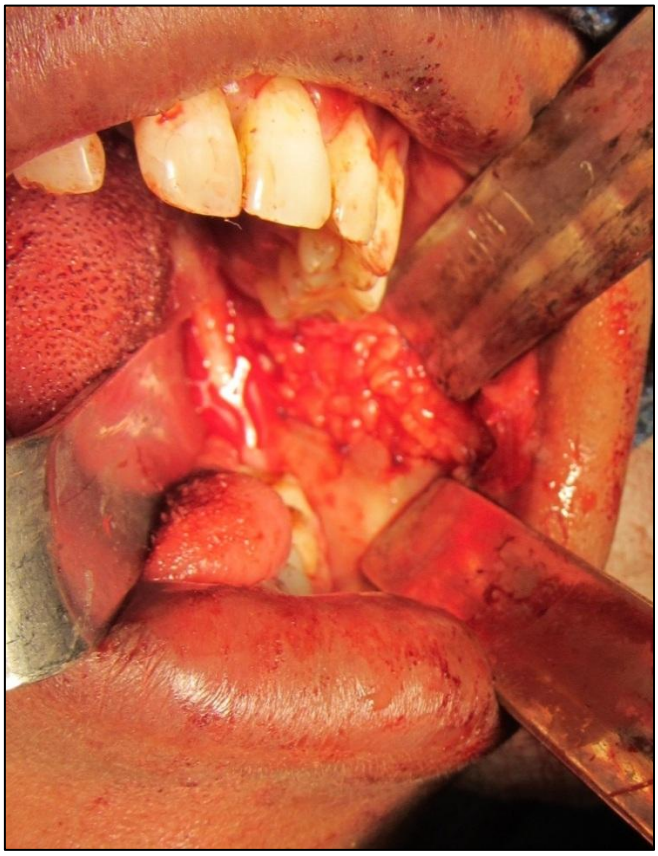
Exposure of buccal fat pad graft through defect after dissection (Right side)



Exposure of buccal fat pad graft through defect after dissection (Left side)



Buccal fat pad graft sutured over the defect (Right side)



Buccal fat pad graft sutured over the defect (Left side)

Healing after one week

Healing after three months

Preoperative mouth opening

Postoperative mouth opening of 40mm after 3 months

OBSERVATION AND RESULTS

This prospective study was carried out to evaluate the application of extended nasolabial flap versus buccal fat pad graft in the surgical management of oral submucous fibrosis for improvement of mouth opening and relieving the symptoms.

A total of 8 patients (6 males and 2 females) were included in the study with age group between 21-65 years (mean 37.25 years). The group 1 included 2 male and 2 female patients with age group between 27-65 years (mean 45 years), while group 2 included 4 male patients with age group between 21-40 years (mean 29.5 years).

All patients presented with positive history of deleterious chewing habits involving some form of areca nut for variable duration. According to classification given by Khanna and Andrade, 2 patients were classified to group III (moderately advanced cases) and rest all patients were classified to group IVa (advanced cases with mouth opening of 2-15 mm)

Patients were distributed randomly to both the groups. Mouth opening was measured for each patient at various stages of treatment procedure. These stages were,

1. Preoperative mouth opening
2. Intraoperative mouth opening
3. 1 month postoperative mouth opening
4. 3 months postoperative mouth opening

These measurements were recorded and the statistical analysis of obtained measurements was performed.

Table-1 shows the mouth opening at preoperative, intraoperative, 1 month postoperative and 3 months postoperative stage for patients treated with extended nasolabial flap.

Table-1

Group 1 (Extended nasolabial flap) patients:

S. N.	Patient name	Age/sex	Pre-operative mouth opening	Intra-operative mouth opening	1 month post-operative mouth opening	3 months post-operative mouth opening
1.	Kalimutthu	65/ F	2 mm	40 mm	25 mm	10 mm
2.	Badre Aalam	27/ M	15 mm	50 mm	40 mm	43 mm
3.	Rahima Bi	43/ F	5 mm	40 mm	30 mm	25 mm
4.	Selvaraj	45/ M	12 mm	45 mm	38 mm	42 mm

Table-2 shows the mouth opening at preoperative, intraoperative, 1 month postoperative and 3 months postoperative stage for patients treated with buccal fat pad graft.

Table-2

Group 2 (Buccal fat pad graft) patients:

S. N.	Patient name	Age/sex	Pre-operative mouth opening	Intra-operative mouth opening	1 month post-operative mouth opening	3 months post-operative mouth opening
1.	Ganesh	28/ M	8 mm	44 mm	40 mm	25 mm
2.	Balaji	29/ M	10 mm	45 mm	40 mm	38 mm
3.	Kumar	40/ M	14 mm	45 mm	42 mm	43 mm
4.	Vinoth	21/ M	15 mm	45 mm	42 mm	40 mm

Table-3 shows the mean values obtained for preoperative, intraoperative, 1 month postoperative and 3 months postoperative mouth opening for patients treated with extended nasolabial flap.

Table-3

	Minimum value	Maximum value	Mean value
Preoperative mouth opening	2 mm	15 mm	8.5 mm
Intraoperative mouth opening	40 mm	50 mm	43.75 mm
1 month postoperative mouth opening	25 mm	40 mm	33.25 mm
3 months postoperative mouth opening	10 mm	43 mm	30 mm

Table-4 shows mean values obtained for preoperative, intraoperative, 1 month postoperative and 3 months postoperative mouth opening for patients treated with buccal fat pad graft.

Table-4

	Minimum value	Maximum value	Mean value
Preoperative mouth opening	8 mm	15 mm	11.75 mm
Intraoperative mouth opening	44 mm	45 mm	44.75 mm
1 month postoperative mouth opening	40 mm	42 mm	40.50 mm
3 months postoperative mouth opening	25 mm	43 mm	36.50 mm

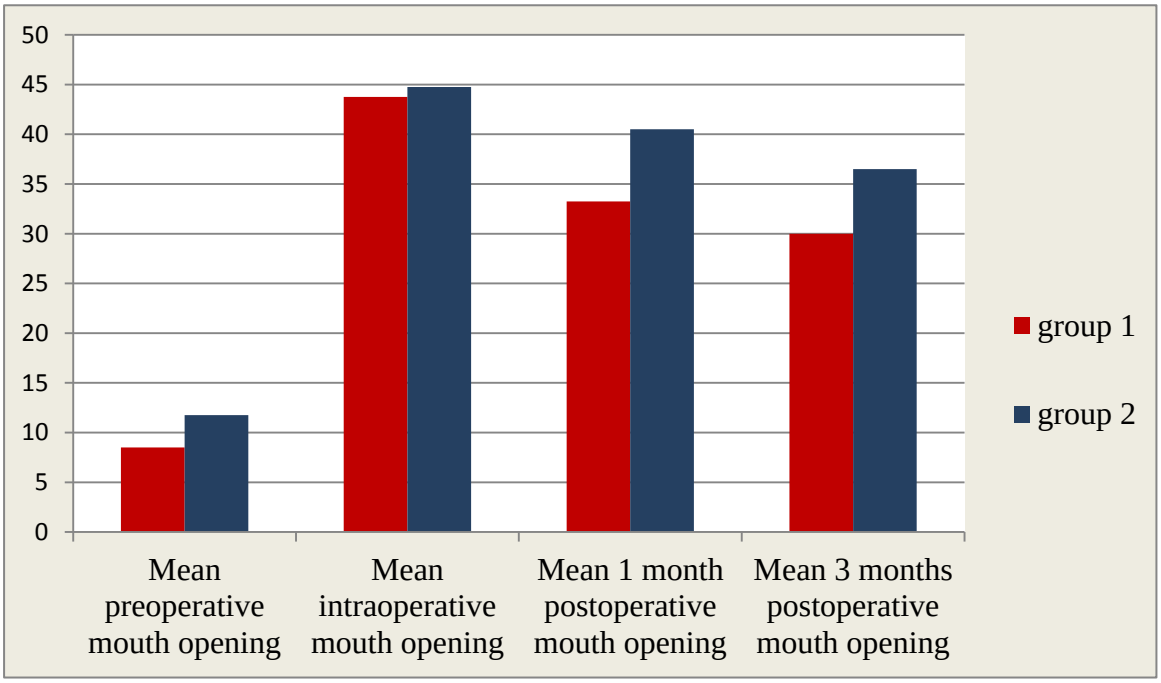
Table-5 shows the mean increase in mouth opening after 3 months for group 1 and group 2.

Table-5

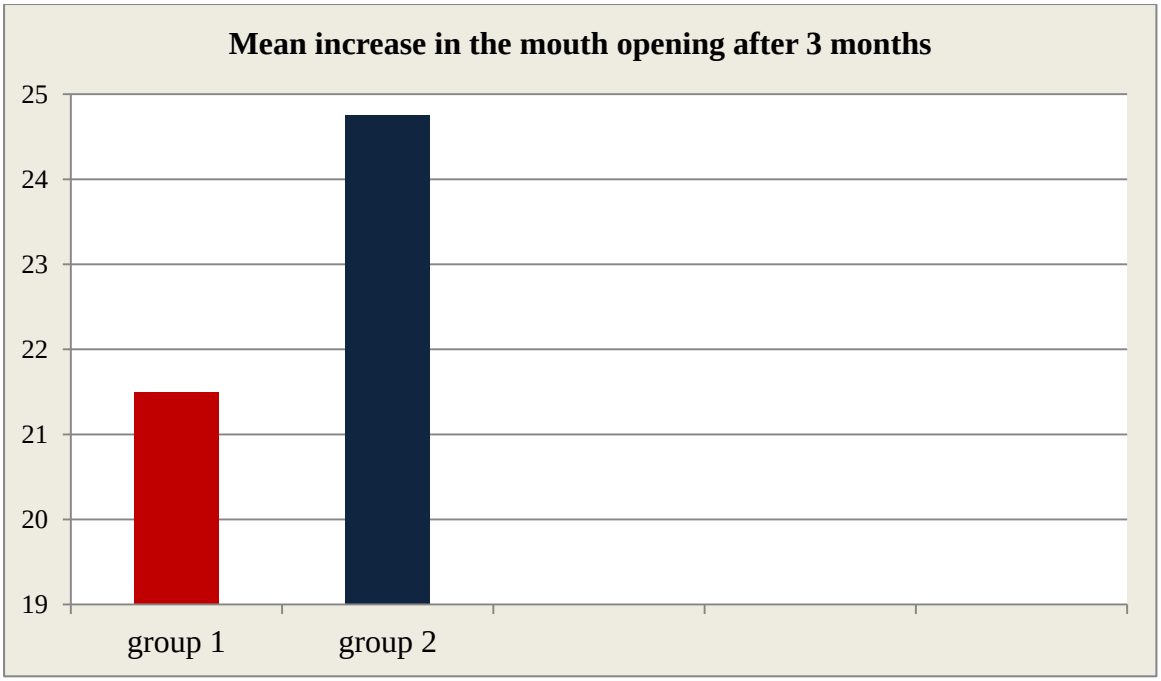
	Mean preoperative mouth opening	Mean 3 months postoperative mouth opening	Mean increase in mouth opening after 3 months
Group 1	8.5 mm	30 mm	21.50 mm
Group 2	11.75 mm	36.50 mm	24.75 mm

Interpretation of results

The mean age of group 1and group 2 was 45 years and 29.5 years respectively. The mean preoperative mouth opening in group 1 was 8.5 mm and in group 2 was 11.75 mm. In group 1, mean 3 months postoperative mouth opening was 30 mm and in group 2, was 36.50 mm. The mean increase in group 1 after 3 months of postoperative period was 21.50 mm and in group 2 was 24.75 mm.



Graph-1



Graph-2

DISCUSSION

Oral submucous fibrosis is a precancerous condition with high prevalence in the Indian subcontinent. It commonly involves the soft palate, palatal fauces, uvula, tongue, labial mucosa but most frequently it involves the buccal mucosa and retromolar areas. It is believed that it starts from the posterior part of the oral cavity and subsequently involves the anterior parts. In our series, buccal mucosa and retromolar areas were most commonly involved followed by labial mucosa, soft palate, palatal fauces and tongue.

Oral submucous fibrosis has wide variety of etiological factors, among which chewing betel nut and tobacco is the most common and accepted one.[50,51,52] In our study, all patients had a positive history of chewing some form of betel nut or tobacco or combination of both for variable duration.

The diagnostic criteria for oral submucous fibrosis in early stages include burning sensation of mucosa, intolerance to hot and spicy food, mucosal blanching, vesiculation, excessive salivation, pigmentation change, ulceration, altered taste sensation, dryness of mouth, and recurrent stomatitis. There is fibrosis followed by stiffness in the buccal mucosa, soft palate and faucial pillars. Fibrotic bands become palpable which run vertically in the check region and circumferentially in the lips. Gradually, this leads to inability in opening the mouth. In advanced cases, shrunken and bud like uvula, limited function of soft palate and restricted tongue movements are seen.[50,51] The majority of these diagnostic features were observed in our patients with varying degree.

The various conservative treatment modalities for oral submucous fibrosis were proposed. These include oral administration of vitamins,[53,54,55] antioxidants[55,56] and Iron supplements,[55] Zinc,[57] topical application of Gold,[58] Iodides as well as

intralesional injections of Hyaluronidase,[55] Hydrocortisone,[55] Placental extract,[55] Triamcinolone,[55] Interferon gamma,[59] and enzymes like Collagenase,[55,60] Chymotrypsin.[55] Drugs like Pentoxifylline, Buflomedil Hydrocloride and Nylidrin were used to improve the circulation to the affected area.[55,61] All our patients had positive history of the treatment with one or more of the conservative modalities but reported that they were not useful.

Progressive restriction of mouth opening has health related and social implications. Surgical therapy is beneficial in cases presenting severe trismus and which are not responding to the medicinal treatment. After surgical therapy, oral mucosa should regain and retain its normalcy and there should be reduction in the risk of oral cancer. Relapse is the common complication after surgical release of trismus.

Mere cutting of the fibrotic bands followed by forcible mouth opening and allowing secondary epithelization left an unsatisfactory rigid buccal mucosal surface even when attempts were made to reduce collagen formation by insertion of steroid impregnated packs.[50] It resulted in scar formation and recurrence of trismus. Additional procedures like temporalis myotomy and bilateral coronoidectomy can be performed to enhance mouth opening.[62,63]

Results with skin grafting to cover the raw areas have been disappointing as the incidence of shrinkage, contracture and rejection of graft was found to be very high because of the poor oral conditions and subsequent recurrence of symptoms.[12] Split thickness skin grafts along with bilateral temporalis muscle myotomy or coronoidectomy were effective, but have the drawbacks of secondary contracture formation in temporalis tendon and muscle and pterygomandibular raphae, which appears to be the principal cause of restricted mouth opening.[50] Recurrence of

symptoms was common in the studies conducted by Khanna & Andrade,[12] Lai. D.R.[64] and Glenn Morawetz et al.[58] The other limitation split thickness skin graft is the morbidity associated with donor site along with maintenance of mouth opening post operatively for 7 to 10 days which is the most unpleasant and uncomfortable experience for the patient.[50]

Palatal island flaps based on greater palatine artery to cover the defects of oral submucous fibrosis has been employed by Khanna and Andrade.[12] The technique of utilizing the palatal island flaps was found to be simple. But the use of island palatal flap has limitations such as its involvement with fibrosis and second molar tooth extraction is required for flap cover without tension.[65] Bilateral palatal flaps leave a large raw area on the palatal bones. Sometimes the defect created may be large and local flaps may not be able to cover the entire defect.

Tongue flaps have also been used for treating oral submucous fibrosis but have disadvantages such as, postoperative dysphagia, disarticulation, the risk of postoperative aspiration and need for additional surgery for detachment of the pedicle.[12] The involvement of tongue in oral submucous fibrosis often precludes its use in treating oral submucous fibrosis.[12,62]

Application of amniotic membrane is of little benefit when used in single layer over deep buccal defects.[64] Human placental grafts can also be applied to cover the defects. It has shown little beneficial results when combined with submucosal injection of Dexamethasone.[4]

Bilateral radial artery forearm free flaps[15] and the bipaddled radial forearm flap[16] from single donor site require micro vascular expertise. The procedure is time consuming and technically demanding. Donor site morbidity as well as unsightly scar

formation are other disadvantages. The flaps are hairy and 40% of the patients require secondary de-bulking procedures. Extractions of third molars are required to avoid flap inclination between teeth. Flaps from anterolateral thigh[18] were used for reconstruction of buccal defects after release of fibrosis but drawbacks include donor site morbidity and need for de-bulking of flap.

Present study was conducted with an aim of achieving results in terms of mouth opening and reduction of symptoms by transecting the fibrous bands and reconstruction using extended nasolabial flap or buccal fat pad graft and comparing the results of both techniques in achieving the same. This prospective study included 8 patients with clinically and histopathologically confirmed diagnosis of oral submucous fibrosis. They were further divided into two groups, group 1 and group 2 receiving extended nasolabial and buccal fat pad graft respectively as an interposition material.

The nasolabial flaps has advantages such as, the donor site is in the same operating field, reliable and rich vascularity, provides versatality in design, proximity to the defect, ease of flap elevation, supple skin, thus aiding in increasing mouth opening and causing minimal esthetic deformity, while the disadvantages being intraoral hair growth, temporary widening of oral commissure and occasional hypertropic scar at the donor site.[21]

The use of nasolabial flaps in treatment of oral submucous fibrosis is more suitable for juxtaposed defects, in particular those of buccal mucosa, and is increasingly popular. The nasolabial flap provides a good example of the transposition flap principle in which the unavoidable tension is transferred from the defect to the donor area where there is sufficient tissue elasticity to absorb it (Huffstadt, 1961).

Defects of the ala, the tip and the bridge of the nose, and the upper and lower lip resulting from trauma or surgical excisions are particularly suitable for reconstruction with nasolabial flaps provided that the tissue to be transposed is unscarred and has not been previously irradiated. The colour and texture match is excellent and in older patients, the donor scar is quite inconspicuous.[66]

The versatility of the nasolabial flap depends upon several factors. Owing to a dual blood supply from both facial and ophthalmic arteries, the flap can be either superiorly or inferiorly based.[67] Intraorally placed nasolabial flap provides 15 cm^2 of durable lining,[68] a mobile pedicle with sufficient blood supply to be safely transposed at the time of primary tumor resection even after ligation of the facial artery.

The classic nasolabial flap is an oblique cheek flap based either superiorly or inferiorly. Often used for alar and lip reconstruction, this type of flap has been suggested in the past for palatal and floor of the mouth reconstruction. The flap usually extends inferiorly to an area lateral to the nasolabial fold, but it can be carried more inferiorly to the area of the oral commissure to provide a longer more versatile flap.[67] As this part of the cheek remains soft and supple even many years after repair, this led to development of the application of bilateral nasolabial flaps to cover the defect created by excision of fibrotic bands, by Kavarana and Bhathena[69] with promising results in 3 cases.

Nasolabial flap can be either cutaneous, subcutaneous, musculocutaneous or island nasolabial flaps. In our study we employed bilateral modified single-stage winged extended nasolabial island flaps[21] in all our 4 patients. The mean age of group 1 was 45 years. The length of the flap was adequate to cover the intraoral defect and layered closure of donor site was achieved to minimize postoperative extraoral scar.

In our study, the 3 months postoperative mouth opening in Group 1 subjects (who received extended nasolabial flap) was in the range of 10 mm to 43 mm with mean value of 30 mm. The mean increase in the group 1 after 3 months of postoperative period was 21.50 mm.

Intraoperative complications like damage to facial vessels, parotid duct and branches of facial nerve were not encountered in any of the 4 patients included in the study. None of the flaps showed either bluish or whitish discoloration in the postoperative phase and no infection was encountered in any of our cases. Complications such as flap loss, flap avulsion, obstructive sialadenopathy or wound dehiscence were not encountered in our series. Intraoral hair growth was observed in 2 male patients from fifth post-operative day which was managed by regular trimming. The donor site healed uneventfully in all our cases. Although the scars were perceptible in all cases, they were readily accepted by the patients. In our series, one 65 year old female patient did not co-operate for vigorous postoperative exercise therapy and the condition relapsed in 3 months.

Buccal fat pad graft has advantages such as, rich vascular supply, minimal donor site morbidity, ease of surgery which can be performed under local anaesthesia on an outpatient basis, improvement in physiologic functions of cheek after surgery, good patient acceptance, and minimal postoperative morbidity while disadvantages being anterior reach of the graft are limited and limited use for larger defects.

Buccal fat pad by virtue of its anatomic position and the ease with which it can be accessed and mobilized without causing any noticeable defect in the cheek or mouth was felt to be reliable interposition material.[25] The procedure, considering the anatomic proximity of the donor and the recipient site, is not a prolonged one. The

graft can be approached through the same buccal incision, which was used to release the fibrosis. Should it fail, the consequences are not serious, as other options are open. The bulk of buccal fat pad in our series was found to be adequate in all cases and it maintained its position as interposition material post operatively, similar to the findings of Lai D.R,[64] Yeh,[20] Rapidis[24] and M.Ganizo.[70]

Yeh[20] obtained the mean postoperative mouth opening value of 31.2mm over a follow up period of mean 21.3 months. In our study, the mean age of group 2 was 29.5 years. The 3 months postoperative mouth opening range in Group 2 subjects (who received buccal fat pad graft) was 25 mm to 43 mm with mean value of 36.50 mm. Improvement in the physiologic functions like suppleness and elasticity of the buccal mucosa on clinical examination did indeed had a good correlation with the original study conducted by Yeh.[20] The graft began to show signs of epithelization from 2nd week. This observation is similar to studies done by Alper Alkan,[25] Yeh,[20] Tideman[28] and Rapidis.[24]

No intraoperative or postoperative complications were found in group 2 patients. One patient of group 2 in our series experienced a relapse with mouth opening of 25 mm after 3 months, which unfortunately was due to the non-co-operation of the patient with regard to postoperative mouth opening exercises.

All patients noted significant reduction in symptoms of intolerance to spice and ulcerations in the period of 3 months follow up, except in one 65 year old female in whom the condition relapsed.

Whatever the graft being used, the treatment should be coupled with cessation of betel quid or gutkha chewing, daily mouth opening excercises, and proper nutrition in order to manage properly both early and advanced stages of oral submucous fibrosis.

SUMMARY AND CONCLUSION

Oral submucous fibrosis is a chronic disabling disorder. Advanced cases with severe trismus require surgical correction. Reconstruction of the defect after incision and release of fibrous bands is done with variety of options such as skin grafts, island palatal mucoperiosteal flap, bilateral tongue flap, the superficial temporal fascia flap with split thickness skin graft, radial forearm flaps, flaps from anterolateral thigh, artificial dermis, buccal fat pad graft and nasolabial flaps which are having their own advantages and disadvantages.

The present study was conducted to assess the postsurgical improvement in mouth opening following use of extended nasolabial flap or buccal fat pad graft in the surgical management of oral submucous fibrosis.

In the present study, buccal fat pad graft proved to give better results as the interposition material as it has good patient acceptance, rapid epithelization, minimal donor site morbidity and minimal intra and postoperative complications.

Vigorous mouth opening exercises, cessation of habits and improvement in the nutritional status are must for better results post operatively.

However, further studies should be conducted, to evaluate the efficacy of buccal fat pad graft in large sample size.

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ANNEXURES

CASE REPORT FORM

COMPARISON OF EXTENDED NASOLABIAL FLAP VERSUS BUCCAL FAT PAD GRAFT IN THE SURGICAL MANAGEMENT OF ORAL SUBMUCOUS FIBROSIS- A PROSPECTIVE STUDY

Patient's Name : _____

Age/ Sex : _____

Patient's Identification No. : _____

Contact Address : _____

Contact No : _____

Institution : TN. Govt. Dental College & Hospital,
Chennai - 600 003.

Centre : Dept. of Oral & Maxillofacial Surgery,
TN. Govt. Dental College and Hospital,
Chennai - 600 003.

Date : _____

DETAILS OF SURGERY

Procedure followed : Excision of fibrous bands and reconstruction by extended nasolabial flap or buccal fat pad graft.

Duration of Surgery :

Any other information :

Details of Drug therapy :

Name of the Investigator :

Signature of Investigator :

INFORMED CONSENT

STUDY TITLE: "COMPARISON OF EXTENDED NASOLABIAL FLAP VERSUS BUCCAL FAT PAD GRAFT IN THE SURGICAL MANAGEMENT OF ORAL SUBMUCOUS FIBROSIS- A PROSPECTIVE STUDY."

Patient's Identification No: _____ Patient's Name: _____

Patient's DOB: _____ _____ _____

dd mm yyyy

I confirm that I have read and understood the Information Sheet for the above study. I have had the opportunity to ask questions and all my questions and doubts have been answered to my complete satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

I understand that the Clinical study personnel, the Ethics Committee and the Regulatory Authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information released to the third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.

I agree not to withhold any information about my health from the investigator and will convey the same truthfully.

I agree to take part in the above study and to comply with the instructions given during the study and to faithfully co-operate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms.

I hereby consent to participate in this study & I understand that I'll be treated by surgical procedure under general anaesthesia for my restricted mouth opening and associated symptoms and I was well informed about the complications associated with it & I agree for the same.

I consent to give my medical history, undergo complete physical examination and diagnostic tests including hematological, biochemical and urine examination etc.

Signature / Thumb Impression: _____ Place_____Date_____

Patient's Name & Address: _____

_____

Signature of the Investigator: _____Place_____ Date_____

Study Investigator's Name: _____

Institution: _____

* Signature of the Witness: _____Place_____ Date_____

* Name & Address of the Witness _____

_____ *Mandatory for uneducated patients (Where thumb impression has been provided above)

INFORMATION SHEET

We are conducting a study on **"Comparison of extended nasolabial flap versus buccal fat pad graft in the surgical management of oral submucous fibrosis- A prospective study**" among the patients attending Tamil Nadu Govt. Dental College & Hospital, Chennai. For this study, we are selecting patients.

The purpose of this study is to evaluate the application of nasolabial flap versus buccal fat pad graft in the surgical management of oral submucous fibrosis.

The identity of the patients participating in the research will be kept confidential throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in the study is voluntary. You are free to decide whether to participate in the study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study.

Name of the patient Signature/ Thumb impression

Name of the investigator Signature Date

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

வாய் இறுக்கு நோய்க்கு உதடு மூக்கு தோல் தொங்கல் மற்றும் கன்னத்திண்டு ஒட்டு அறுவைசிகிச்சை முறைகளை ஒப்பீடு செய்தல்-தொலைநோக்கு ஆய்வு

ஆராய்ச்சி நிலையம் : அரசு பல் மருத்துவக் கல்லூரி
சென்னை-600 003.

பங்கு பெறுபவரின் பெயர் :

பங்கு பெறுபவரின் எண் :

பங்கு பெறுபவரின் பிறந்த தேதி : _____/_____/_____
தேதி மாதம் வருடம்

அறுவை சிகிச்சை சம்பந்தமாக நான் மேலே கூறப்பட்ட தகவல் படிவத்தை முழுமையாக படித்துப் பார்த்தேன் என்று உறுதி கூறுகிறேன்.

நான் இது தொடர்பான அனைத்து கேள்விகளுக்கும் நிறைவான பதில்கள் பெறப்பட்டேன்.

இந்த ஆய்வின் எனது பங்கு தன்னிச்சையானது என்றும் எந்த நேரத்திலும் இந்த ஆய்வில் இருந்து சட்ட உரிமைகள் பாதிக்கப்படாமல் விலகிக்கொள்ள சம்மதிக்கிறேன்.

மருத்துவ ஆய்வு அதிகாரிகள் எனது சிகிச்சை தொடர்பான பதிவேடுகளை பார்வையிடவும் எந்த நேரத்திலும் ஆய்வில் இருந்து நான் விலகினாலும் பார்வையிட சம்மதிக்கிறேன். எனது அடையாள குறிப்புகள் மூன்றாவது நபருக்கு தெரிவிக்கப்படமாட்டாது என்று புரிந்து கொண்டேன்.

ஆய்வு அறிக்கைகளை பயன்படுத்தவும் வெளியிடவும் நான் சம்மதிக்கிறேன். ஆய்வாளர் உனது மருத்துவக் குறிப்புகளை வெளியிட தடையாக இருக்கமாட்டேன் என உண்மையாக சம்மதிக்கிறேன்.

நான் இந்த ஆய்வுக்கு முன்னர் கூறிய மருத்துவ குறிப்புகளின்படியும் உண்மையாக சம்மதிக்கிறேன். மேலும் எனக்கு உடல்நிலை சரியில்லாத பட்சத்தில் ஆய்வாளர்களுக்கு தெரியப்படுத்த சம்மதிக்கிறேன்.

பொது மயக்க மருத்துவ முறையில் வாய் இறுக்கு நோய்க்கு உதடு மூக்கு தோல் தொங்கல் மற்றும் கன்னத்திண்டு ஒட்டு அறுவைசிகிச்சை முறையில் எனக்கு சிகிச்சை அளிக்கப்படுகிறது என்பதை நான் அறிந்து கொண்டேன். இந்த அறுவை சிகிச்சை முறையில் ஏற்படும் அனைத்து பக்க விளைவுகளையும் மருத்துவர் மூலம் அறிந்துகொண்டு இந்த ஆய்விற்கு என்னை உட்படுத்திக்கொள்கிறேன்.

நான் எனது மருத்துவ குறிப்புகளை தரவும் மேலும் முழு உடல் பரிசோதனைக்கும் இரத்தம் சிறுநீர் மற்றும் உயிர்வேதியியல் நோய் அறிதல் சோதனைகளுக்கும் முழு ஒப்புதல் அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம் ..... இடம் ..... தேதி.....
கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....
ஆய்வாளரின் கையொப்பம் ..... இடம் ..... தேதி.....
ஆய்வாளரின் பெயர்.....